

Please add Claims 50-127 as follows:

Dab 1

50. A method for producing spray-dried particles having improved stability of a protein comprising:

(a) combining a protein, a phospholipid and a co-solvent, said co-solvent including an aqueous solvent and an organic solvent, to form a mixture; and

(b) spray-drying said mixture to produce spray-dried particles having improved stability of the protein;

wherein the particles consist essentially of the protein and the phospholipid and wherein the phospholipid is present in the particles in an amount of at least about 10 weight percent.

C1

51. The method of Claim 50 wherein the spray-dried particles consist of the protein and the phospholipid.

52. The method of Claim 50 wherein the phospholipid is selected from the group consisting of phosphatidylcholines, phosphatidylethanolamines, phosphatidylglycerols, phosphatidylserines, phosphatidylinositols and combinations thereof.

53. The method of Claim 50 wherein the protein is human growth hormone.

54. The method of Claim 50 wherein the protein is present in the spray-dried particles in an amount ranging from about 1 to about 90 weight %.

55. The method of Claim 50 wherein protein stability is measured by SEC-HPLC.

56. The method of Claim 50 wherein the spray-dried particles retain at least about 70% protein integrity when stored at about 25°C and about 60% relative humidity conditions for six weeks.

57. The method of Claim 50 wherein the spray-dried particles retain at least about 50% protein integrity when stored at about 40°C and about 75% relative humidity conditions for six weeks.

58. The method of Claim 50 wherein the protein is a therapeutic, prophylactic or diagnostic agent.

59. The method of Claim 50 wherein the protein and phospholipid concentration in said mixture is at least 0.1 weight/volume %.

60. The method of Claim 50 wherein the co-solvent includes an alcohol.

61. The method of Claim 50 wherein the organic solvent is present in the co-solvent in a concentration of at least 50 volume %.

62. The method of Claim 50 wherein the spray-dried particles have a tap density less than about 0.4 g/cm³.

63. The method of Claim 62 wherein the spray-dried particles have a tap density less than about 0.1 g/cm³.

64. The method of Claim 63 wherein the spray-dried particles have a tap density less than about 0.05 g/cm³.

65. The method of Claim 62 wherein the spray-dried particles have a median geometric diameter of between about 5 microns and about 30 microns.

66. The method of Claim 62 wherein the spray-dried particles have an aerodynamic diameter of between about 1 micron and about 5 micron.

67. The particles produced by the method of Claim 50.

68. A method comprising administering to the respiratory tract of a patient in need of treatment, prophylaxis or diagnosis an effective amount of the spray-dried particles produced by the method of Claim 50.

69. A method for producing spray-dried particles having improved stability of a peptide comprising:
(a) combining a peptide, a phospholipid and a co-solvent, said co-solvent including an aqueous solvent and an organic solvent, to form a mixture; and
(b) spray-drying said mixture to produce spray-dried particles having improved stability of the peptide;
wherein the particles consist essentially of the peptide and the phospholipid and wherein the phospholipid is present in the particles in an amount of at least about 10 weight percent.

70. A method for producing spray-dried particles having improved stability of a protein comprising:
(a) combining a protein, a phospholipid and a co-solvent, said co-solvent including an aqueous solvent and an organic solvent, to form a mixture; and
(b) spray-drying said mixture to produce spray-dried particles having improved stability of the protein;
wherein the particles consist essentially of the protein and the phospholipid and the phospholipid is a phospholipid endogenous to the lung.

71. The method of Claim 70 wherein the spray-dried particles consist of the protein and the phospholipid.

72. The method of Claim 70 wherein the phospholipid is selected from the group consisting of phosphatidylcholines, phosphatidylethanolamines, phosphatidylglycerols, phosphatidylserines, phosphatidylinositols and combinations thereof.

73. The method of Claim 70 wherein the phospholipid is present in the particles in an amount ranging from about 1 to about 99 weight percent.

- 74. The method of Claim 70 wherein the protein is human growth hormone.
- 75. The method of Claim 70 wherein the protein is present in the spray-dried particles in an amount ranging from about 1 to about 99 weight %.
- 76. The method of Claim 70 wherein protein stability is measured by SEC-HPLC.
- 77. The method of Claim 70 wherein the spray-dried particles retain at least about 70% protein integrity when stored at about 25°C and about 60% relative humidity conditions for six weeks.
- 78. The method of Claim 70 wherein the spray-dried particles retain at least about 50% protein integrity when stored at about 40°C and about 75% relative humidity conditions for six weeks.
- 79. The method of Claim 70 wherein the protein is a therapeutic, prophylactic or diagnostic agent.
- 80. The method of Claim 70 wherein the combined protein and phospholipid concentration in said mixture is at least 0.1 weight/volume %.
- 81. The method of Claim 70 wherein the co-solvent includes an alcohol.
- 82. The method of Claim 70 wherein the organic solvent is present in the co-solvent in a concentration of at least 50 volume %.
- 83. The method of Claim 70 wherein the spray-dried particles have a tap density less than about 0.4 g/cm³.
- 84. The method of Claim 83 wherein the spray-dried particles have a tap density less than about 0.1 g/cm³.

85. The method of Claim 84 wherein the spray-dried particles have a tap density less than about 0.05 g/cm³.
86. The method of Claim 83 wherein the spray-dried particles have a median geometric diameter of between about 5 microns and about 30 microns.
87. The method of Claim 83 wherein the spray-dried particles have an aerodynamic diameter of between about 1 micron and about 5 micron.
88. The particles produced by the method of Claim 70.
89. A method comprising administering to the respiratory tract of a patient in need of treatment, prophylaxis or diagnosis an effective amount of the spray-dried particles produced by the method of Claim 70.
90. A method for producing spray-dried particles having improved stability of a peptide comprising:
 - (a) combining a peptide, a phospholipid and a co-solvent, said co-solvent including an aqueous solvent and an organic solvent, to form a mixture; and
 - (b) spray-drying said mixture to produce spray-dried particles having improved stability of the peptide;
wherein the particles consist essentially of the peptide and the phospholipid and the phospholipid is a phospholipid endogenous to the lung.
91. A method for producing spray-dried particles having improved stability of a protein comprising:
 - (a) combining a protein, a phospholipid and an organic solvent, to form a mixture; and
 - (b) spray-drying said mixture to produce spray-dried particles having improved stability of the protein;

wherein the particles consist essentially of the protein and the phospholipid and wherein the phospholipid is present in the particles in an amount of at least about 10 weight percent.

92. The method of Claim 91 wherein the spray-dried particles consist of the protein and the phospholipid.
93. The method of Claim 91 wherein the phospholipid is selected from the group consisting of phosphatidylcholines, phosphatidylethanolamines, phosphatidylglycerols, phosphatidylserines, phosphatidylinositols and combinations thereof.
94. The method of Claim 91 wherein the protein is human growth hormone.
95. The method of Claim 91 wherein the protein is present in the spray-dried particles in an amount ranging from about 1 to about 90 weight %.
96. The method of Claim 91 wherein protein stability is measured by SEC-HPLC.
97. The method of Claim 91 wherein the spray-dried particles retain at least about 70% protein integrity when stored at about 25°C and about 60% relative humidity conditions for six weeks.
98. The method of Claim 91 wherein the spray-dried particles retain at least about 50% protein integrity when stored at about 40°C and about 75% relative humidity conditions for six weeks.
99. The method of Claim 91 wherein the protein is a therapeutic, prophylactic or diagnostic agent.
100. The method of Claim 91 wherein the protein and phospholipid concentration in said mixture is at least 0.1 weight/volume %.

101. The method of Claim 91 wherein the solvent includes an alcohol.
102. The method of Claim 91 wherein the spray-dried particles have a tap density less than about 0.4 g/cm³.
103. The method of Claim 102 wherein the spray-dried particles have a tap density less than about 0.1 g/cm³.
104. The method of Claim 103 wherein the spray-dried particles have a tap density less than about 0.05 g/cm³.
105. The method of Claim 102 wherein the spray-dried particles have a median geometric diameter of between about 5 microns and about 30 microns.
106. The method of Claim 102 wherein the spray-dried particles have an aerodynamic diameter of between about 1 micron and about 5 micron.
107. The particles produced by the method of Claim 91.
108. A method comprising administering to the respiratory tract of a patient in need of treatment, prophylaxis or diagnosis an effective amount of the spray-dried particles produced by the method of Claim 91.
109. A method for producing spray-dried particles having improved stability of a protein comprising:
 - (a) combining a protein, a phospholipid and an organic solvent, to form a mixture; and
 - (b) spray-drying said mixture to produce spray-dried particles having improved stability of the protein;
wherein the particles consist essentially of the protein and the phospholipid and the phospholipid is a phospholipid endogenous to the lung.

110. The method of Claim 109 wherein the spray-dried particles consist of the protein and the phospholipid.
111. The method of Claim 109 wherein the phospholipid is selected from the group consisting of phosphatidylcholines, phosphatidylethanolamines, phosphatidylglycerols, phosphatidylserines, phosphatidylinositol and combinations thereof.
112. The method of Claim 109 wherein the phospholipid is present in the particles in an amount ranging from about 1 to about 99 weight percent.
113. The method of claim 109 wherein the protein is human growth hormone.
114. The method of Claim 109 wherein the protein is present in the spray-dried particles in an amount ranging from about 1 to about 99 weight %.
115. The method of Claim 109 wherein protein stability is measured by SEC-HPLC.
116. The method of Claim 109 wherein the spray-dried particles retain at least about 70% protein integrity when stored at about 25°C and about 60% relative humidity conditions for six weeks.
117. The method of Claim 109 wherein the spray-dried particles retain at least about 50% protein integrity when stored at about 40°C and about 75% relative humidity conditions for six weeks.
118. The method of Claim 109 wherein the protein is a therapeutic, prophylactic or diagnostic agent.
119. The method of Claim 109 wherein the combined protein and phospholipid concentration in said mixture is at least 0.1 weight/volume %.
120. The method of Claim 109 wherein the solvent includes an alcohol.



121. The method of Claim 109 wherein the spray-dried particles have a tap density less than about 0.4 g/cm³.
122. The method of Claim 121 wherein the spray-dried particles have a tap density less than about 0.1 g/cm³.
123. The method of Claim 122 wherein the spray-dried particles have a tap density less than about 0.05 g/cm³.
124. The method of Claim 121 wherein the spray-dried particles have a median geometric diameter of between about 5 microns and about 30 microns.
125. The method of Claim 121 wherein the spray-dried particles have an aerodynamic diameter of between about 1 micron and about 5 micron.
126. The particles produced by the method of Claim 109.
127. A method comprising administering to the respiratory tract of a patient in need of treatment, prophylaxis or diagnosis an effective amount of the spray-dried particles produced by the method of Claim 109.

REMARKS

Claims 1-49 have been cancelled and new Claims 50-127 have been added. Support for new Claims 50-127 is found throughout the specification and in the originally filed claims. No new matter has been introduced.

Specifically, Claim 50 has been redrafted to include, in addition to the elements recited in the originally filed Claim 1, the elements of original Claims 2 and 7. In addition, present Claim 50 further recites that the phospholipid is present in the particles in an amount of at least about 10 weight percent. Specific support for the amount of phospholipid present in the particles is found at page 10, line 30 of the written description. Present Claim 69 is directed to peptides and is similar in format to newly submitted Claim 50.